

REMARKS

Claims 50, 52, 55-63, 65-68, 70, 72-79, and 82-84 are pending in the above-referenced application. Claims 50, 52, 55, 57, 59, 61, 62, 68, 70, 82, and 84 are amended. Claims 50, 55, 56, 58-63, 65-68, 70, and 82-84 are rejected under 35 U.S.C. § 112, first paragraph; claims 57 and 70 are rejected under 35 U.S.C. § 112, second paragraph; claims 79, 50, 55, 56, 58-63, 79, and 82-84 are rejected under 35 U.S.C. § 102(b); claims 50, 55, 56, 58-63, 65, 66, 67, 68, 70, and 82-84 are rejected under 35 U.S.C. § 103(a); and claims 50, 52, 55, 56, 58-63, 65-67, 70, 79, and 82-84 are rejected under the judicially created doctrine of obviousness-type double patenting. Each of the rejections is addressed below.

Support for the Amendments

Support for the amendment of the claims is found throughout the specification and claims as originally filed. No new matter has been added. For example, support for the amendment of claim 70 to recite "TGF- α ," "TGF- β ," and "TNF- α " is found at page 20, lines 17 and 18 of the specification as originally filed.

Amendment and cancellation of the claims here are not to be construed as an acquiescence to any of the rejections/objections made in the instant Office Action or in any previous Office Action, and were done solely to expedite prosecution of the application. Applicants hereby reserve the right to pursue the claims as originally filed, or substantially similar claims in one or more subsequent patent applications.

Rejections under 35 U.S.C. § 112

Claims 50, 55, 56, 58-63, 65-68, 70, and 82-84, which are directed to methods for inducing formation of new blood vessels in a mammal having chronic or acute ischemia, are rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. Applicants respectfully disagree and traverse the rejection.

However, without acquiescing in any way to the rejection and in order to expedite prosecution of the application, Applicants have amended claim 50, from which claims 55-63, 65-68,

and 70 depend, claim 82, from which claim 83 depends, and claim 84, to include the language of claim 52, which was not rejected as lacking enablement. In particular, claims 52 and 84 now recite administering an effective amount of VEGF and GM-CSF; and claim 82 now recites administering an effective amount of GM-CSF. Applicants note that the Examiner acknowledged that the specification enables such methods (Office action mailed August 9, 2006, page 3, third full paragraph, to page 4, line 3). Specifically, the Examiner stated that the specification enables “a method for inducing formation of new blood vessels in a mammal having chronic or acute ischemia, wherein the method comprises administering to the mammal an effective amount of a vascular endothelial growth factor” or the hematopoietic factor GM-CSF. Accordingly, the rejection under 35 U.S.C. § 112, first paragraph, should be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 57 and 70 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. This rejection is overcome by the present amendment of claim 57, which now depends from claims 50 and 52, and by the amendment of claim 70 to correct a typographical error. Claim 70 now recites TGF- α and TGF- β . Accordingly, the rejection under 35 U.S.C. § 112, second paragraph, should also be withdrawn.

Rejection under 35 U.S.C. § 102

Claims 50, 55, 56, 58-63, 79, and 82-84 are rejected under 35 U.S.C. § 102(b). Claim 79 is rejected as allegedly anticipated by Takeshita et al., (J. Clin. Invest. 93:662-670, 1994); claims 50, 55, 56, 58-63, 65, 55, 79, and 82-84 are rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Aharinejad et al., (Bone 16:315-324, 1995). Applicants respectfully disagree and traverse the rejection.

However, without acquiescing in any way to the rejections and in order to expedite prosecution and facilitate allowance of the application, Applicants have amended claims 50, 82, and 84, as described above, and submit that the rejections do not apply to claims 50, 55, 56, 58-63, 79, and 82-84. Claims 50, 82, and 84 have been amended to incorporate the recitation of claim 52, which was not rejected under 35 U.S.C. § 102(b). In particular, claim 50 is now directed to methods

for inducing formation of new blood vessels in a mammal having chronic or acute ischemia, where the method comprises administering to the mammal an effective amount of a vascular endothelial growth factor (VEGF) and granulocyte-macrophage colony stimulating factor (GM-CSF); claim 82 is now directed to methods for inducing formation of new blood vessels in a mammal having chronic or acute ischemia, and increasing endothelial progenitor cell (EPC) frequency, where the method comprises administering granulocyte-macrophage colony stimulating factor (GM-CSF); and claim 84 is now directed to methods for inducing formation of new blood vessels in a mammal having chronic or acute ischemia, wherein the method comprises administering to the mammal an effective amount of a vascular endothelial growth factor (VEGF) and granulocyte-macrophage colony stimulating factor (GM-CSF) and increasing endothelial progenitor cell (EPC) frequency by at least about 20% as determined by a standard EPC isolation assay. Accordingly, the rejection under 35 U.S.C. § 102(b) should be withdrawn.

Rejection under 35 U.S.C. § 103

Claims 50, 55, 56, 58-63, 65, 66, 67, 68, 70, and 82-84 are rejected under 35 U.S.C. § 103(a). In particular, claims 50, 55, 56, 58-63, 68, 70, and 82-84 are rejected as allegedly obvious over Hammond et al., (U.S. Patent No. 5,880,090; hereinafter "Hammond") in view of Asahara et al., (Science 275:964-967, 1997; hereinafter "Asahara"); claim 67 is rejected over Hammond in view of Asahara or Kawakami (Brain Res. 697:104-111, 1995; hereinafter "Kawakami"); claims 50, 55, 56, 58-63, 65, 66, 68, 70, and 82-84 are further rejected over Hammond in view of Asahara and Aiuti et al., (J. Exp. Med. 185:111-120, 1997); claim 84 is further rejected over Takeshita et al., (J. Clin. Invest 93: 662-670, 1994). Applicants respectfully disagree and traverse the rejections for the reasons of record and reiterate those reasons herein.

However, without acquiescing in any way to the rejections and in order to expedite prosecution and facilitate allowance of the application, claims 50, 82, and 84 have been amended to incorporate the recitation of claim 52, which was not rejected under 35 U.S.C. § 103(a). In particular, claims 50, 82, and 84 and the claims that depend there from, are now directed to methods for inducing formation of new blood vessels in a mammal having chronic or acute ischemia

featuring granulocyte-macrophage colony stimulating factor (GM-CSF). Accordingly, the rejection under 35 U.S.C. § 103(a) should also be withdrawn.

Double Patenting

Claims 50, 52, 55, 56, 58-63, 65-67, 70, 79, and 82-84 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 3-4 and 11 of U.S. Patent No. 5,980,887. Applicants respectfully disagree and traverse the rejection. Applicants will address the obviousness-type double patenting rejection upon a finding that the claims (that will be pending upon entry of the amendments presented herein) are in condition for allowance, but for the instant double patenting rejection.

Claims 50, 52, 55, 56, 58-63, 65-68, 70, 79, and 82-84 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 49-52, 54-59, 65, and 68 over copending Application No. 10/696,391. Claims 50, 52, 55, 56, 58-63, 65-67, 79, and 82-84 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 49 and 58-60 of copending Application No. 10/714,574. Applicants will determine whether the filing of a terminal disclaimer is appropriate to overcome the provisional obviousness-type double patenting rejection once otherwise allowable subject matter has been determined.


CONCLUSION

In view of the above amendment, Applicants believe the pending application is in condition for allowance. Therefore, Applicants respectfully request entry of the amendments and remarks presented herein, favorable reconsideration and withdrawal of all pending rejections, and issuance of a Notice of Allowance. However, if the Examiner disagrees, Applicants respectfully request the Examiner to contact the undersigned at the telephone number indicated below **prior** to the mailing of an Office action.

Applicants believe that no fee is due to consider the present amendment. Nevertheless, the Director is hereby authorized to charge or credit any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105. Although it is not believed that additional fees are needed to consider this submission, the Examiner is authorized to charge our Deposit Account No. **04-1105** should such fee be deemed necessary.

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Respectfully submitted,

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